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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,126	11/05/1999	AKSEL BUCHTER-LARSEN	674509-2020	6366

20999 7590 05/23/2003

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EXAMINER
KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
1638	16

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No.	Applicant(s)	
	09/423,126	BUCHTER-LARSEN ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9,21 and 26-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9,21 and 26-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-8, 10-20, and 22-25 have been cancelled. Claims 1, 9, 21, and 26-39 are pending.

The rejection of Claims 21 and 28-39 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicant's amendments and arguments.

Claim Rejections - 35 USC § 112

Claims 1, 21, 26-28, 30-31, 34-35, and 38-39 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's arguments filed 1/18/03 have been fully considered but they are not persuasive.

Applicant asserts that they have provided relevant identifying characteristics for a genus of glucan lyases in the form of nucleotide sequences and have demonstrated the functional properties of said sequences showing a correlation between function and structure (response page 5). In order to satisfy the written description requirement for a claimed genus Applicant must describe a representative number of DNAs encompassed by the genus or structural features unique to the genus. See *University of California V. Eli Lilly and Co.,* 119 F.3d 1559, 1569; 43

USPQ2d 1398 (Fed. Cir. 1997). Applicant has satisfied neither. Applicant describes six sequences (SEQ ID NO: 7-12 that encode SEQ ID NO: 1-6) sequences presumably from a single organism, and only four of which show significant sequence relatedness (SEQ ID NO: 7, 8, 11, 12 encode SEQ ID NO: 1, 2, 5, 6) and are presumed to encode glucan lyase. Applicant does not provide adequate written description to support the broad claims drawn to methods requiring DNAs from any and all organisms that encode glucan lyase. Moreover, Applicant does not provide adequate written description to support a genus of DNAs with at least 75%, 85%, or 90% identity to SEQ ID NO: 7, because Applicant has only described a single DNA, namely SEQ ID NO: 7, encompassed by the genus. Applicant is advised that amendment of the claims to recite "a nucleotide sequence encoding a glucan lyase enzyme having at least 75% sequence identity to the amino acid of SEQ ID NO: 1" would obviate the rejection as Applicant has described two sequences encompassed by the genus. Furthermore, such claim language is supported by page 9, lines 30-32 of the specification, and such claim language is more meaningful since it requires relatedness at the amino acid level.

Claims 1, 21, 26-31, 33-35, and 37-39 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant's arguments filed 1/18/03 have been fully considered but they are not persuasive.

Applicant asserts that when applying the *Wands* factors to the instant facts; it is clear that enablement exists to practice the claimed invention (response page 6-7). The claimed invention is a process of expressing a glucan lyase in a plant to endogenously produce anhydrofructose for

use as an antioxidant in a foodstuff made from the transformed plant and to improve the transformation efficiency of said plant. Applicant has failed to provide guidance for achieving adequate levels of anhydrofructose as an antioxidant in a transgenic plant such that it would be useful as a nutrient supplement in a foodstuff or would allow for increases in the efficiency of transformation. Applicant has not provided any working examples of transformation of any glucan lyase into any plant and the state of the art teaches that high levels of enzyme production in transgenic plants are not routinely obtained. Given the quantity of experimentation required to make or use the invention due to the lack of working examples and limited guidance in the specification, the unpredictability in the art of plant transformation and for making transgenic foodstuffs, and in light of the breadth of the claims drawn broadly to a method of plant transformation with any one of a multitude of non-exemplified glucan lyases encoding genes from a host of non-exemplified sources for modification of plant metabolism to produce anhydrofructose in a myriad of non-exemplified plants to either improve their transformation efficiency or endogenously express an antioxidant in a food product made from said plant, the claims are not enabled.

Claim Rejections - 35 USC § 103

Claims 21, 28, and 32-39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yu *et al.* (U.S. Patent 6,013,504) in view of Perl *et al.* (Nature Biotechnology, Vol. 14 May, 1996).

Claims 1, 9, 26-27 and 29-31 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yu *et al.* (U.S. Patent 6,013,504) in view of Perl *et al.* (Nature Biotechnology, Vol. 14 May, 1996).

Applicant's arguments filed 1/18/03 have been fully considered but they are not persuasive.

In response to applicant's argument (page 8 lines 15-21) that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant asserts that it was not obvious that plants could be transformed to produce functional antioxidants, *in situ* and that there is no teaching to suggest otherwise. Applicant asserts that Yu *et al.* only relates to transformation, that the microorganisms taught by Yu *et al.* cannot be applied to the transformation of plants (response pages 8-9). Applicant's arguments are clearly misguided. The reference of Yu *et al.* teaches expression of a cDNA from a fungal source expressing a glucan lyase in a host capable of the starch degradation pathway for the purpose of producing anhydrofructose, an antioxidant. Perl *et al.* teach transformation of grape and provide motivation for enhanced efficiency of grape transformation by the addition of anhydrofructose to the medium.

Applicant further asserts that the addition of an antioxidant to a foodstuff is also not obvious (response pages 9 line 25 to page 10 line 6). However, nature has already provided for antioxidants in foodstuffs that occur in the form of vitamins found already in high levels in fruits and vegetables and food products made therefrom such as wine.

Applicant asserts that the method of the present invention is a method based on Perl (response page 10 line 13) and is not necessarily an improvement over the teaching of Perl, but rather an alternative method (response page 10 lines 18-22). An alternative method would work as well as another alternative method and thus is an obvious variant. Clearly, Applicant recognizes the advantage for an antioxidant in the transformation process as taught by Perl and thus Applicant's methods are only obvious variants.

Furthermore, Applicant asserts it was found that by transforming grapes with any one of the sequences presented as SEQ ID NO: 7-12, encoding glucan lyase, the transformation was assisted by the *in situ* preparation of the antioxidant anhydrofructose (response page 10 lines 14-17). The Examiner begs to differ, clearly there is no evidence to support this conclusion.

All claims remain rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the receptionist, whose telephone number is (703) 308-0196.

Russell Kallis Ph.D.
May 14, 2003

Amy Nelson

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
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